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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,714	01/14/2000	YECHIEL SHAI	SHAI=2	4669

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/367,714	SHAI ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11,13,21,38 and 40-52* is/are pending in the application.

4a) Of the above claim(s) *21 and 50-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11, 13, 38, 40-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the amendment filed 9/21/04, claims 1-6, 8, 12, 14, 20, 27-29, 35, 39 have been cancelled, claims 9-11, 13, 21, 38 amended, and claims 40-52 added.

Claims 9-11, 13, 21, 38, 40-52 are now pending.

Claims 21 and 50-52 are withdrawn from consideration since they do not encompass the elected specie. The elected specie is the following (boldface = "D" isomer), which was identified (original claim 13) as a peptide falling within the scope of original claim 1, part (2):

K-L-**L**-**L**-K-L-K-**L**-K-**L**-L-K-NH_2

Thus, applicants have identified this peptide as falling outside the scope of original claim 1, part (5). Similarly, the elected specie does not fall within the scope of original claim 1, part (4).

Claims 9-11, 13, 38, 40-49 are examined in this Office action.

Applicants' arguments filed 9/21/04 have been considered and found persuasive in part. The previously imposed rejection of claims 27-29 under 35 U.S.C. §112, first paragraph (enablement) is withdrawn. The rejection of claims 8-13, 37, 39 under 35 U.S.C. §112 (new matter) is also withdrawn. The rejection of claims 8-11 as anticipated by Shai (*J. Biol. Chem.* **271**, 7305, 1996) is withdrawn.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11, 13, 38, 40-49 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification asserts that the claimed peptides are effective to cause lysis of pathogenic cells. However, there is no evidence that this is the case. Certainly, there is data in the specification (pages 48-53) which shows that selected peptides can inhibit growth of bacteria, fungi, and adenocarcinoma cells. (Also, tables 1 and 2, pages 28-30). However, merely because a compound can inhibit growth of pathogenic cells does not mean that this inhibition has occurred as a result of cytolysis.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or

unpredictability of the art, and breadth of the claims. The principle piece of "evidence" in support of this ground of rejection is applicants' own admission (response filed 9/21/04, page 24, last three lines), which is the following:

> "[A] disclosure that peptides inhibit the "growth" of pathogenic cells in no way suggests that the inhibition occurs through cytolysis. In fact, many antibiotics are bacteriostatic in their inhibitory effect and do not result in cytolysis of pathogenic cells.

Additionally, applicants have pointed to the disclosure of Paradies (USP 4,874,850) as providing an example of a compound (gramicidin S) which is effective to inhibit growth of pathogenic cells, but which is not, at the same time, cytolytic to those pathogenic cells. Thus, according to the admission made by applicants, the skilled microbiologist cannot "predict", based on the observation of inhibition of pathogenic cell growth, which compounds will be cytolytic and which will not. In addition, there are no "working examples" which show that the claimed peptides are cytolytic. Further, there is no evidence that the prior art teaches the skilled microbiologist how to determine, from among those compounds which inhibit growth of pathogenic cells, which will also induce cytolysis.

It is noted that there is an unsubstantiated assertion in the specification (e.g., page 6, line 20+) that all peptides falling within the scope of the claims will induce cytolysis. But apart from this assertion, there is no direction or guidance provided in the specification which would teach the skilled microbiologist how to determine which of the peptides that inhibit pathogenic cell growth will also induce cytolysis. The breadth of the claims is great, and

extensive experimentation would be required to synthesize every possible peptide, to then test each peptide for its propensity to inhibit growth of pathogenic cells, and then to determine from the list of peptides thus obtained, which will also induce cytolysis.

Thus, in view of the absence of any direction or guidance presented, the absence of working examples (showing the skilled artisan how to use the peptides to induce cytolysis), the state of the prior art, the unpredictability of the art, and the substantial breadth of the claims, "undue experimentation" would be required to determine which of the peptides encompassed by the claims will induce cytolysis in pathogenic cells.

✧

Claims 9 and 11 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the phrase "the positively charged amino acid". Claim 41, on which claim 9 depends, does not recite either of the following phrases:

a positively charged amino acid

the positively charged amino acid

It is true that claim 41 recites "positively charged amino acids" in the plural. But since the singular of "acids" is not used in claim 41, the phrase "positively charged amino acid" (in claim 9) lacks antecedent basis. This is more than a minor grammatical issue. The question is

whether the "positively charged amino acid" must only be one of those listed, or whether others can be present as well. This issue is particularly important in the case of claim 11, which could potentially be interpreted to require that all amino acids other than Leu, Val and Lys are excluded.

✧

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-11, 40, 41, 47, 48 are rejected under 35 U.S.C §102(e) as anticipated by Maloy (U.S.P. 5,792,831).

Maloy teaches cytolytic peptides containing D-amino acids. Also disclosed (e.g., col 4, line 43, col 5, line 30+, col 27, line 59) is that the peptides are not hemolytic.

In response, applicants have argued that because the term "alpha helix breaker moiety" is no longer present in the claims, the reference no longer applies. Applicants have stated the following (page 18 of 26):

"The new claims do not permit all of the amino acids of the peptide to be of the D-configuration, or all of the chiral amino acids to be of the D-configuration as long as an *alpha*-helix breaker moiety is present."

This particular statement is actually not true, but in any case, many of the disclosed peptides meet the requirements of the claims. That is, even if it were true (but it is not true) that the claims do not permit all of the chiral amino acids to be of the D-configuration as long as an *alpha*-helix breaker moiety is present, the fact is that the stereochemical requirements of the claims are met if the following condition is met:

"at least one but not all of [the] amino acids is D-amino acid"

This requirement is met by each of SEQ ID NOS: 1-8 (of the reference). The examiner will acknowledge that if one were to examine the sequence listings in isolation, it might not be evident that all amino acids other than glycine were of the D-configuration. However, the patent is replete with statements that each amino acid must be either glycine, or else an amino acid of the D-configuration (e.g., col 1, line 15-18). Further, as explicitly stated at col 44, line 48+ , in each of SEQ ID NOS: 2-7 all of the amino acids other than glycine must be of the D-configuration.

SEQ ID NOS: 1-8 of the patent are provided below:

SEQ ID NO:1

Lys-Ile-Ala-Gly-Lys-Ile-Ala-Lys-Ile-Ala-Gly-Lys-Ile-Ala-Lys-Ile-Ala-Gly-Lys-Ile-Ala

SEQ ID NO:2

Gly-Ile-Gly-Lys-Phe-Leu-Lys-Lys-Ala-Lys-Lys-Phe-Gly-Lys-Ala-Phe-Val-Lys-Ile-Leu-Lys-Lys

SEQ ID NO:3:

Gly-Ile-Gly-Lys-Phe-Leu-Lys-Ser-Ala-Lys-LysPhe-Gly-Lys-Ala-Phe-Val-Lys-Ile-Met-Asn-Ser

SEQ ID NO:4:

Gly-Ile-Gly-Lys-Phe-Leu-Lys-Lys-Ala-Lys-Lys-Phe-Gly-Lys-Ala-Phe-Val-Lys-Ile-Met-Lys-Lys

SEQ ID NO:5:

Lys-Leu-Ala-Ser-Lys-Ala-Gly-Lys-Ile-Ala-Gly-Lys-Ile-Ala-Lys-Val-Ala-Leu-Lys-Ala-Leu

SEQ ID NO:6:

Gly-Ile-Gly-Lys-Phe-Leu-Lys-Ser-Ala-Lys-Lys-Phe-Gly-Lys-Ala-Phe-Val-Lys-Ile-Leu-Asn-Ser

SEQ ID NO:7:

Gly-Ile-Gly-Lys-Phe-Leu-Lys-Lys-Ala-Lys-Lys-Phe-Ala-Lys-Ala-Phe-Val-Lys-Ile-Ile-Asn-Asn

SEQ ID NO:8:

Lys-Ile-Ala-Gly-Xaa-Ile-Ala-Lys-Ile-Ala-Gly-Xaa-Ile-Ala-Lys-Ile-Ala-Gly-Xaa-Ile-Ala

. . . .

In addition to the foregoing, various peptides are disclosed which meet the requirements of the claims. See, for example, the peptides listed at col 14, line 50-58; and col 16, line 35+. As stated at col 16, line 62 each amino acid is either glycine, or else is of the D-configuration.

In addition to the foregoing, the peptide disclosed at col 15, 15+ meets the requirements of the claims, as does the peptide at col 16, line 52+.

Thus, the claims encompass peptides in which (a) at least one glycine is present, and (b) all amino acids other than glycine are of the "D" configuration. Many of the peptides disclosed in Maloy meet these limitations.

The rejection is maintained.

✧

Claims 9-11, 40-42, 47, 48 are rejected under 35 U.S.C §102(a) as anticipated by Lee (WO 97/02286).

Lee discloses antibiotic peptides which contain both D- and L-amino acids. Also disclosed (e.g., page 8, line 10+) is that the peptides do not lyse red blood cells. In particular, Lee discloses the following peptide in which one or more of the L-amino acids (but not all of them) have been replaced with D-amino acids (table 11, pages 18-19):

KKYIKKVFVFK-NH_2

In the same table, the peptide of SEQ ID NO: 85 is disclosed. With the exception of glycine, all of the amino acids in SEQ ID NO: 85 are of the D-configuration. Further, there is no indication that any of these peptides would be found in nature if all D-amino acids were replaced with the corresponding L-amino acids.

Thus, the claims are anticipated.

✧

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 9-11, 38, 40, 41, 47, 48 are rejected under 35 U.S.C. §103 as being unpatentable over Shai (*J. Biol. Chem.* **271**, 7305, 1996).

As indicated previously, Shai teaches (table I, p. 7306) several peptides that are antibacterial but non-hemolytic, and which would otherwise meet the requirements of the claims were it not for the exclusion of SEQ ID NOS: 1, 12, 14 and 23. As indicated in the previous Office action, this rejection is directed to close structural homologs of SEQ ID NOS; 1, 12 and 14; for example, replacing a phenylalanine residue with phenethylglycine.

In response, applicants have argued that "the examiner's reasoning here is just plain wrong". In particular, applicants have focused on the examiner's assertion that the following amino acid is an amino acid which is not found in nature ("X" represents

ethylenediamine):

$$H_2N\text{-}CH(CH_2\text{-}CH_2\text{-}COX)COX$$

Applicants' representative has stated the following (page 20 of 26):

> "...contrary to the examiner's assertion, this residue is not an amino acid at all and therefore cannot be an amino acid not occurring in nature. While this compound can be designated a chemical derivative of a natural amino acid, no peptide biochemist would regard this compound as being encompassed within the definition of an amino acid. In fact, this same question was posed to several biochemists, including Prof. Shai, a co-inventor of the instant application and a biochemist recognized as an expert in the area of peptide biochemistry and author or co-author of innumerable scientific publications, and the response was unanimous this is clearly not an amino acid."

However, applicants have provided neither evidence nor reasoning as to why the skilled peptide chemist would come to believe that the compound in question is not an amino acid. The compound contains both an amino group and a carbonyl group. It is true that the compound contains two amide groups, but the same can be said of glutamine in which the C-terminus is amidated. Further the spatial relationship between the "C-terminal" carbonyl group and the *alpha*-amino group is identical to that which is found in glutamine. The number of carbon atoms which separates the two groups is identical in the amino acid in question versus glutamine. Similarly, the spatial relationship between the "*beta*" carbonyl group and the *alpha*-amino group is identical to that which is found in glutamine. The number of carbon atoms which separates the two groups is identical in the amino acid in question *versus* glutamine. What applicants' representative has provided is not an opinion

by an expert, but rather, an opinion about an opinion, i.e., the opinion of applicants' representative as to the opinion of Yechiel Shai. The examiner maintains that the compound in question is indeed an amino acid. But even if it were true that Yechiel Shai were correct in asserting that the following is not an amino acid *per se*,

$$H_2N\text{-}CH(CH_2\text{-}CH_2\text{-}COX)COX$$

it appears that applicants' representative may not have posed the appropriate question to Yechiel Shai. The question is not simply whether the compound at issue is an amino acid *per se*, but rather, whether the compound meets the criteria for an amino acid which is not found in nature. The term "amino acid" may be somewhat imprecise, and its exact meaning depends on the context of the discussion. For example, aminobenzoic acid is an amino acid, but a biologist who deals only with naturally occurring proteins would not necessarily recognize aminobenzoic acid as an "amino acid", absent further reflection. Another example might be 10, 20-diaminododecanoic acid, i.e., the following:

$$H_2N\text{-}(CH_2)_{10}CH(NH_2)(CH_2)_8\text{-}COOH$$

This amino acid is "not found in nature", but is an amino acid nevertheless. Nor would this latter compound lose its property of being an amino acid if e.g., a hydroxyl group were bonded at position 15 of the carbon chain. In general, if a compound contains an amino group and a carboxyl group, the compound is an amino acid. (A compound which contains multiple amide bonds is another matter, however). The compound at issue meets the criteria for an amino acid that is not found in nature. If the question were posed to

Yechiel Shai as to whether the compound at issue is an amino acid which is not found in nature, it would be difficult to argue in specific terms what structural feature is lacking.

Next, applicants have argued that the reference must disclose the following genus of peptides in order for the rejection to be valid:

> "...a non-natural synthetic peptide having at least 6 residues and a net positive charge which is greater than +1, said peptide comprising hydrophobic, positively charged and optionally polar amino acid residues, wherein at least one, but not all of such amino acid residues is a D-amino acid, said peptide having a ratio of hydrophobic to positively charged amino acids such that the peptide is cytolytic to pathogenic cells but does not cause cytolysis of red blood cells"

However, it is not the case that the reference must disclose the claimed genus. Rather, it is sufficient that the reference disclose just one peptide that falls within the scope of the claimed genus. Certainly, the requirement for 6 or more amino acids is met, since the peptides have 33 amino acids. The disclosed peptides have between 1 and 3 amino acids of the "D" configuration, and the rest are of the "L" configuration. The disclosed peptides contain Leucine, which is "hydrophobic", and lysine, which is positively charged. In addition, each of the peptides is positively charged (at neutral pH). Next, consider the following phrase:

"peptide having a ratio of hydrophobic to positively charged amino acids such that".

Without exception, any peptide that contains both hydrophobic and positively charged amino acids can be said to be characterized by a "ratio" of these two parameters. And as indicated

in the previous Office action, the author of this reference asserts that the disclosed peptides are cytolytic to pathogenic cells but does not cause cytolysis of red blood cells; applicants have presented neither evidence nor an assertion that this particular limitation is not met by the peptides of the reference.

Thus, while it is true that the specific genus of the instant claims is not recited in the reference, there is at least one peptide disclosed in the reference which would render obvious at least one peptide falling within the scope of the instant claims [*In re Shetty* (**195** USPQ 753) and *In re Hass & Susie* (**60** USPQ 544)].

The rejection is maintained.

✧

Claim 38 is rejected under 35 U.S.C. §103 as being unpatentable over Maloy (U.S.P. 5,792,831).

The teachings of Maloy are indicated above. Maloy also discloses (e.g., col 28, line 51+) pharmaceutical compositions containing one of the peptides in combination with a pharmaceutically acceptable carrier. Maloy does not specifically state that the peptide species indicated above should be combined with a pharmaceutically acceptable carrier. However, the indicated peptide species clearly fall within the scope of the disclosed genus, and the artisan of ordinary skill would recognize that these peptides are among those that can be formulated into a pharmaceutical composition.

In response to the §102 rejection, applicants argued that the claims do not encompass

peptides which meet both of the following conditions: (a) at least one glycine is present, and (b) all amino acids other than glycine are of the "D" configuration. However, a reading of the claim indicates that this particular assertion by applicants is not correct. Thus, the claim is rendered obvious.

✧

Claims 9-11, 38, 40, 41, 47, 48 are rejected under 35 U.S.C. §103 as being unpatentable over Paradies (USP 4,874,850).

As indicated previously, Paradies discloses (col 46, line 34+) that gramicidin S is an antibiotic. Also disclosed (col 47, line 58) that cyclic gramicidin S is not hemolytic. On the page containing columns 67-68 (USP '850), the structure of gramicidin S is provided; it is a cyclic peptide that contains two D-amino acids, and has a charge greater than +1. Paradies does not characterize gramicidin as cytolytic. However, one of ordinary skill would expect that if a compound is cytotoxic to microorganisms, it is cytolytic. Furthermore, as indicated in the previous Office action, this is the implied assertion in the specification.

In response, applicants have argued that the mere observation of inhibition of pathogenic cell growth is not sufficient to conclude that the inhibition has occurred as a result of cytolysis. However, in reviewing all of the data in the specification obtained by contacting the claimed peptides with pathogenic cells, one finds that it is applicants who have implicitly argued that inhibition of cell growth equates with cell

lysis. All of the experiments conducted on pathogenic cells were limited to a showing of inhibition of cell growth. In each case, it is argued in the specification that this amounts to a showing of cytolysis. Thus, by applicants own criteria, the peptides of Paradies must be acting by inducing cytolysis.

Thus, the claims are rendered obvious.

✧

Claims 9-11, 38, 40, 41, 47, 48 are rejected under 35 U.S.C. §103 as being unpatentable over Jacob (USP 5,635,479).

As indicated previously, Jacob discloses peptides that can be used to inhibit growth of cancer cells, and to treat cancer patients. Among the disclosed peptides are SEQ ID NO: 115 and SEQ ID NO: 117 in which all of the chiral amino acids are of the D-configuration, but which peptides also contain glycine. Also disclosed col 22, line 5+ and table I (col 21, line 18+) is that the two peptides (in which all of the chiral amino acids are of the D-configuration) extended life of rats which had been injected with ovarian teratoma cells (see also figures 1-4). The reference does not explicitly state that the peptides are more effective at killing cancer cells than they are at inducing hemolysis.

In response to this ground of rejection, applicants have argued that the rejection is improper because the claims exclude peptides in which there are no L-amino acids. This particular assertion by applicants is incorrect, but in any case the assertion can be

paraphrased as a statement that the claims require at least one L-amino acid to be present. In reality, however, there is no such requirement in the (rejected) claims. As indicated above (the §102 over Maloy), the claims encompass peptides which meet both of the following conditions: (a) at least one glycine is present, and (b) all amino acids other than glycine are of the "D" configuration. For example, both D-(SEQ ID NO: 115) and D-(SEQ ID NO: 117) meet these requirements (see, e.g., col 21, line 22+).

The rejection is maintained.

✧

Claim 38 is rejected under 35 U.S.C. §103 as being unpatentable over Lee (WO 97/02286).

The teachings of Lee are indicated above. Lee also discloses (page 8, line 21+) pharmaceutical compositions which contain one of the active peptides, and a pharmaceutically acceptable carrier. Lee does not specifically state that the peptides of table 11 should be combined with a pharmaceutically acceptable carrier. However, the peptides of table 11 clearly fall within the scope of the disclosed genus, and the artisan of ordinary skill would recognize that the peptides of table 11 are among those that can be formulated into a pharmaceutical composition.

Thus, the claim is rendered obvious.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension

of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

D. Lukton 11/30/04

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

JON WEBER
SUPERVISORY PATENT EXAMINER